Alan J. Bernstein
Law Offices of Alan J. Bernstein, Ltd.,
10 S. LaSalle St., Ste. 1420,
Chicago, IL 60603
Telephone: 312-726-2755

Troy A. Brenes, SBN 249776
(*Pro Hac Vice pending*)
BRENES LAW GROUP, P.C.
100 Spectrum Center Drive, Suite 330
Irvine, CA 92618
tbrenes@breneslawgroup.com
Telephone: (949) 397-9360
Facsimile: (949) 607-4192
Attorney for Plaintiff

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

TAMMY KEEL, Plaintiff, vs. BG MEDICAL, LLC; ASPIDE MEDICAL; and DOES 1 through 10, inclusive, Defendants.	Case No.: **COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL**

Plaintiff TAMMY KEEL ("Plaintiff"), by and through her undersigned counsel, brings this Complaint against Defendants BG MEDICAL, LLC; ASPIDE MEDICAL and Does 1 through 10 and in support thereof states the following:

1. This is a device tort action brought on behalf of the above-named Plaintiff arising out of the failure of Defendants' Surgimesh XB surgical mesh device ("Surgimesh" or "SurgimeshXB"). As a result, Plaintiff suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. The Plaintiff respectfully seeks all damages to which she may be legally entitled.

/ / /

I. PARTIES & JURISDICTION

2. Plaintiff TAMMY KEEL ("Plaintiff") is, and was, at all relevant times, a citizen and resident of the State of Alabama and the United States.

3. Defendant BG MEDICAL, LLC (hereinafter "BG MEDICAL), now is, and at all times relevant to this action was, was incorporated under the laws of Illinois and has its principal place of business and headquarters in the state of Illinois. No owners of the BG Medical are citizens or reside in Alabama. BG Medical's agent for service of process is Andrew J. Kelleher, Jr. and is located at 102 South Wynstone Park Dive, North Barrington, Illinois 60010.

4. BG MEDICAL is the exclusive distributor for Defendant, ASPIDE MEDICAL d/b/a SURGIMESH. Dating back to at least 2009 and continuing until at least 2021, BG Medical was substantially involved in marketing, distribution, and post-market surveillance of the SurgimeshXB hernia mesh device. BG Medical independently created and maintains numerous methods to market and promote the SurgimeshXB, including multiple websites, brochures, labeling materials, testimonial pages, marketing campaigns, sales representatives, promotional activities and interactions with physician societies, and other promotional tactics. BG Medical markets itself as a "World specialist in surgical textile implants." BG Medical has also been involved in the recruitment and payment to physicians to study and promote the use of SurgimeshXB. Upon information and belief, BG Medical may also have been involved in the design of the SurgimeshXB.

5. Per BG Medical, ASPIDE MEDICAL d/b/a SURGIMESH (hereinafter "ASPIDE") designed and manufactured the SurgimeshXB implanted in Plaintiff. Plaintiff has no reason to dispute these claims at this time. Aspide is foreign (French) entity most closely resembling a corporation, and its headquarters and principal place of business is located at 246 Allee Lavoisier, 42350 La Talaudiere, France.

6. BG Medical has advised Plaintiff's counsel that Aspide is defunct and is no longer functioning as a company. In another case filed by Plaintiff's counsel regarding the same mesh products, Aspide failed to respond to the Complaint and has taken no action to defend itself.

7. As it now stands, it does not appear that any entity, whether BG Medical or Aspide, is taking responsibility to continue to comply with Food and Drug Administration regulations requiring the post-market surveillance, adverse event investigations and reporting, and continued risk management regarding the SurgimeshXB product.

8. Does 1 through 10, are currently unknown but may have liability due to involvement in the design, manufacture, promotion, labeling, post-market surveillance, or distribution of the SurgimeshXB implanted in Plaintiff, and/or are liable to Plaintiff due to fraudulent transfer of assets involving Aspide. If and when the identity and involvement of Does 1 through 10 is discovered, Plaintiff will amend the Complaint to indicate their identity, involvement, and basis for liability.

9. Hereinafter, BG MEDICAL, ASPIDE and Does 1-10 shall collectively be referred to as "Defendants."

10. This Court has diversity jurisdiction over this matter as complete diversity exists between Plaintiff and all BG Medical and Aspide.

11. Defendants have conducted business and derived substantial revenue from within the State of Illinois and have sufficient minimum contacts and intentionally availed themselves of the benefits of Illinois so as to render the exercise of jurisdiction over Defendants by the Illinois courts consistent with traditional notions of fair play and substantial justice.

12. ASPIDE through its exclusive distributorship with BG MEDICAL with respect to the product at issue in the case at bar, has made or performed contracts or promises substantially connected to the State of Illinois.

13. Venue is proper in this Court as a substantial part of the conduct giving rise to this Complaint occurred in Lake and Cook counties of Illinois.[1] This includes the marketing, promotion, labeling, and post-market surveillance by BG Medical regarding the SurgimeshXB. Additionally, contracts were negotiated and entered into between BG Medical and Aspide in this state. Upon information and belief, Plaintiff further alleges that Aspide commonly shipped manufactured

[1] BG Medical has submitted sworn testimony in another case that it moved its headquarters from Cook County to Lake County in 2018.

SurgimeshXB to Illinois to then be distributed by BG Medical to other states, including the SurgimeshXB implanted in Plaintiff.

II. STATEMENT OF FACTS

14. At all relevant times, each of the Defendants designed, developed, manufactured, licensed, marketed, distributed, sold and/or placed SurgimeshXB in the stream of commerce, deriving substantial revenue therefrom.

15. All acts and omissions of each Defendant as described herein were done by its agents, servants, employees, representatives, and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

16. At all times hereinafter mentioned, upon information and belief, Defendants were and up until the time of the filing of this complaint were business entities actually doing business in the State of Illinois.

17. At all times hereinafter mentioned, Defendants were engaged in the business of designing, manufacturing, advertising, marketing, and selling surgical mesh products including the Surgimesh XB product, and in pursuit of this business, transacted business within the State of Illinois and contracted to provide goods and services in the State of Illinois and others.

18. At all times hereinafter mentioned, upon information and belief, Defendant committed tortious acts inside the State of Illinois, which caused injury to Plaintiff.

19. At all times hereinafter mentioned, upon information and belief, Defendants expected or should reasonably expect its acts to have consequences in all states of the union, including Illinois.

20. Defendants obtained "clearance" to market the Surgimesh XB product under Section 510(k) of the Medical Device Amendments to the Food, Drug, and Cosmetic Act.

21. Section 510(k) permits the marketing of medical devices if the device is substantially equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of the device. The FDA explained the difference between the 510(k) process and the more

rigorous "premarket approval" ("PMA") process in its amicus brief filed with the Third Circuit in *Horn v. Thoratec Corp.*, which the court quoted from:

> A manufacturer can obtain an FDA findings of 'substantial equivalence' by submitting a premarket notification to the agency in accordance with section 510(k) of the [Food Drug and Cosmetic Act.] 21 U.S.C. § 360(k). A device found to be 'substantially equivalent' to a predicate device is said to be 'cleared' by the FDA (as opposed to "approved' by the agency under a PMA.

376. F.3d 163, 167 (3d. Cir. 2004). A pre-market notification submitted under 510(k) is thus entirely different from a PMA, which must include data sufficient to demonstrate that the product involved is safe and effective.

22. In *Medtronic, Inc.* v. *Lohr*, the U.S. Supreme Court similarly described the 510(k) process, observing:

> If the FDA concludes on the basis of the [manufacturer's] § 510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed without further regulatory analysis…. The § 510(k) notification process is by no means comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in average of 20 hours …. As on commentator noted: "The attraction of substantial equivalence to manufacturers is clear. Section 510(k) notification required little information, rarely elicits a negative response form the FDA, and gets processed quickly.

518 S. 470, 478-79 (1996). The court have repeatedly held that a Section 510(k) clearance is not a determination of safety.

23. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared the manufacturer and distributors "remain under an obligation to investigate and report any adverse associated with the drug…and must periodically submit any new information that may affect the FDA's previous conclusions about the safety, effectiveness, or labeling …." This obligation extends to post-market monitoring of adverse events/complaints.

24. SurgimeshXB is a non-absorbable synthetic mesh, made of non-knitted, non-woven fibers of polypropylene, one surface of which is coated with silicone.

25. SurgimeshXB is marketed for use in the repair of hernias and soft tissue deficiencies, including placement next to the bowel.

26. The silicone coating is supposed to allow the mesh to be placed safely next to the bowel by preventing the mesh from adhering to the bowel, colon, or omentum.

27. Defendants falsely represented to the FDA, the public, and Plaintiff's prescribing physician that the SurgimeshXB is safer and more effective than other available hernia mesh devices due to its design.

28. Defendants' false and unsupported claims include, but are not limited to, the following:

a. SurgimeshXB provides superior patient outcomes compared to all other hernia mesh devices;

b. SurgimeshXB is the optimal hernia mesh design and allows for optimal outcomes, reduced patient complication rates, reduced recurrence rates, and has the safest track record compared to other hernia mesh devices;

c. SurgimeshXB's design would reliably prevent adhesions from forming to the device and decreased the risk of adhesions compared to other barrier mesh devices;

d. SurgimeshXB's design would lead to complete, strong, and full incorporation of the mesh into the abdominal wall, and that this would occur within 12 days;

e. SurgimeshXB's design provides superior incorporation compared to all other hernia mesh devices;

f. SurgimeshXB's design prevents shrinkage/contraction of the device after implantation unlike other hernia mesh devices.

g. SurgimeshXB's design leads to a flexible repair that prevents patient pain from the device unlike other hernia repair devices;

h. SurgimeshXB's design protects the device from infection;

i. SurgimeshXB's design limits inflammatory response to low levels and will not cause shrinkage/contraction;

j. That SurgimeshXB is a lightweight hernia mesh design and thus will not cause significant foreign body response or patient pain.

29. Defendants made these claims to the FDA, healthcare providers, including Plaintiff's prescribing physician, via promotional brochures, their marketing websites, labeling materials included with the SurgimeshXB packaging, sales calls by sales personnel, booth presentations at conferences, paid speakers at various physician group events, sponsoring and influencing the outcome of medical studies, emails, and other ways.

30. Defendants knew these statements were untrue at the time they were made, including long before Plaintiff's device was distributed, based on information gained in the pre-market design process and real-world post-market adverse events reported to and investigate by them.

31. Many years before Plaintiff's SurgimeshXB was manufactured and distributed by Defendants, they knew that the SurgimeshXB's design was not reasonably safe for its intended and reasonably foreseeable use (hernia repair via intraperitoneal mesh placement) and was certainly not the "optimal design" that improved patient safety and reduced the risk of complications when compared to all other hernia mesh devices. In fact, Defendants knew and had reason to know that the complications rates associated with the SurgimeshXB actually far exceeded those of other available hernia mesh devices, including for: mesh adherence to bowel, colon, and omentum; organ perforation; infection; chronic pain; recurrence; mesh shrinkage/contracture; severe inflammatory response or foreign body reaction; migration; mesh rupture; bowel obstruction; never injury; seroma; abscess; sexual dysfunction; biofilms; and wound dehiscence.

32. Contrary to the Defendants marketing claims, Defendants knew the SurgimeshXB is a heavyweight mesh that induces a strong foreign body and inflammatory response, which can and does lead to a serious patient complications including, among others, infection, contraction/shrinkage, chronic pain, adhesions, bowel perforation, fistula, rupture and recurrence. As recognized in the literature, heavyweight mesh devices like the SurgimeshXB lead to a more significant foreign body reaction, inflammatory response and patient pain.

33. The polypropylene material used in the manufacture of the SurgimeshXB is not inert. Once implanted in the body, the polypropylene begins to degrade leading to severe inflammatory response and continuing cycle of degradation and inflammation. Surface degradation also causes

flaking of the polypropylene, which increases the surface area of host tissue exposed to the biomaterial and, in turn, increasing the host Foreign Body Response ("FBR") and accelerating the material degradation. Additionally, the degradation of the polypropylene in the SurgimeshXB causes microscopic fissures to form on the surfaces of the polypropylene filaments, creating a nidus for infection and biofilm. This risk can be and is mitigated by other manufacturers by using antioxidants in the manufacturing process to limit the amount of degradation that occurs once implanted. However, Defendants chose not employ this safety step in the manufacturing process. Thus, the SurgimeshXB exposes patients to an unnecessary and greater risk of degradation than other manufacturers.

34. Contrary to Defendants' claims otherwise, Defendants knew or should have known that SurgimeshXB can and often does exhibit substantial contraction/shrinkage once implanted in the body. Defendants knew and should have known that this often causes severe patient injuries including, chronic pain, adhesions to the mesh, perforation and erosion of the bowel or colon, fistulas, device migration, recurrence, meshoma and need for corrective surgery. Further, Defendants knew that it's claims that the SurgimeshXB exhibits substantially less contraction than the other available hernia mesh devices was and is untrue.

35. The SurgimeshXB design is also problematic in that the use of silicone in the mesh exacerbates the development of biofilms by creating an additional impediment to the human body's defenses to infection. Biomaterials research predating the manufacture and distribution of Plaintiff's device, clearly document concerns that permanently implanted products incorporating silicone-coated polypropylene increase the risk for erosion and wound dehiscence.

36. Contrary to Defendants' marketing claims, Defendants knew or should have known that the design of the SurgimeshXB would not reliably or reasonably prevent the SurgimeshXB from becoming adhered to, or eroding or perforating into the bowel, colon, or omentum. Defendants knew such events can and were causing severe patient injuries such as bowel perforation, bowel blockage, chronic pain, infection, sepsis, fistulas, corrective surgeries, and patient death.

37. Contrary to Defendants' claims otherwise, Defendants knew the SurgimeshXB was

more likely to cause adhesions than other available hernia mesh devices.

38. Contrary to Defendants marketing claims otherwise, Defendants' knew that the SurgimeshXB's design was such that it would often not adequately incorporate into the abdominal wall. Defendants knew such failures could and often did lead to severe complications including, but not limited to, recurrence, migration, adhesions, perforation/erosion, infection, and chronic pain. Further contrary to Defendants' claims otherwise, the SurgimeshXB's design does not provide for superior incorporation compared to all other hernia mesh devices.

39. Contrary to Defendants' marketing claims to the contrary, Defendants knew or should have known that the SurgimeshXB caused consumers chronic and substantial pain once implanted. Moreover, Defendants knew or should have known that their claims that the SurgimeshXB was substantially less likely to cause chronic pain was untrue.

40. Contrary to Defendants' marketing claims otherwise, Defendants knew or should have known that the SurgimeshXB's design does not prevent mesh infection or colonization by microbes, nor does it reduce the risk of such adverse events compared to the other hernia mesh devices.

41. Contrary to Defendants' marketing claims otherwise, Defendants knew or should have known that the SurgimeshXB was not the "optimal" hernia mesh design and that it did not in fact have lower complication rates compared to other available hernia mesh devices. In fact, Defendants knew or should have known that the complication rates associated with the SurgimeshXB, including for recurrence, were substantially higher than other available hernia mesh devices.

42. Long before Plaintiff's SurgimeshXB was distributed by Defendants, Defendants knew, or in the exercise of reasonable care should have known, that the SurgimeshXB mesh was not properly manufactured, tested, inspected, packaged, labeled, distributed, marketed, examined, sold, supplied, prepared and/or provided with proper warnings, was not suitable for the purpose it was intended and was unreasonably likely to injure the products' users.

43. Defendants ignored reports from patients and health care providers throughout the

United States of the SurgimeshXB mesh's failure to perform as intended, which led to the severe and debilitating injuries suffered by Plaintiff and numerous other patients. Rather than doing adequate testing to determine the cause of these injuries or rule out the SurgimeshXB product's design as the cause of the injuries, Defendants continued to market SurgimeshXB mesh as a safer and more effective medical device as compared to other available alternative treatment for hernias.

44. Despite having made the many above described false and unsupported statements regarding the SurgimeshXB being safe and effective, being the best possible design of all hernia mesh devices, and having substantially lower complication rates than other hernia mesh devices, Defendants failed to ever take any action to inform the public, the FDA, or Plaintiff's prescribing physician that these statements were not actually true, what the actual severity and frequency of adverse events association with SurgimeshXB were, or what the comparative safety data actually showed. Instead, Defendants, have knowingly and intentionally continued to conceal from Plaintiff and her health providers the true and significant risk associated with the SurgimeshXB mesh.

45. On or about March 25, 2011, Plaintiff was implanted with a 15 x 22 cm SurgimeshXB to repair a ventral incisional hernia. This procedure was performed by Dr. Scott Cassidy.

46. The SurgimeshXB implanted in Plaintiff was designed, manufactured, promoted and distributed by Defendants.

47. Defendants represented the product to be not only safe and effective for this use, but the best and safest design.

48. On October 7, 2020, Plaintiff underwent surgery to correct complications due to mesh failure. The surgery revealed that the SurgimeshXB had malfunctioned and not performed as expected in several ways. The mesh had contracted, did not fully incorporate, became densely adherent to Plaintiff's bowel and omentum, and caused a severe inflammatory and infectious response. As a result of these mesh failures, Plaintiff suffered severe pain and suffering, including chronic pain, necrosis of her omentum, bowel obstruction, and contamination of her abdominal space from the necrosed omentum. Of note, the mesh had become so adhered to the bowel and

omentum, that it took approximately five (5) hours to take down the adhesions.

49. Plaintiff required further surgery on January 13, 2021 for mesh removal due to mesh infection. Approximately 400 milliliters of purulent fluid was evacuated as well as the SurgimeshXB. Instead of performing a mesh repair and further lysis of adhesions, they placed a drain and performed primary closure. Her skin was closed with staples and a wound VAC was placed.

50. Had defendants adequately warned Plaintiff's prescribing physician of the above-described information, said prescribing physician would not have used the SurgimeshXB mesh. Alternatively, said prescribing physician would at minimum have disclosed this information to Plaintiff in order to obtain informed consent and Plaintiff would not have agreed to implantation of the SurgimeshXB.

51. Plaintiff and Plaintiff's physicians used the SurgimeshXB in a manner that was both intended by and foreseeable to Defendants.

52. The Defendants' SurgimeshXB mesh implanted into the Plaintiff was in the same or substantially similar condition as when it left the possession of the Defendants, and in the condition directed by and expected by the Defendants. Plaintiff and Plaintiff's health care providers did not alter the SurgimeshXB in any way that was not intended by and reasonably foreseeable to Defendants.

53. At the time the SurgimeshXB that was implanted in Plaintiff was distributed by Defendants, feasible and safer alternative designs existed. Such designed included substantially more effective barrier technology and lighterweight mesh designs.

54. Defendants advertised, promoted, marketed, sold, and distributed the SurgimeshXB mesh as a safe and effective medical device when Defendants knew or should have known the SurgimeshXB mesh was not safe for its intended purposes and that the SurgimeshXB was failing and causing serious complications at rates substnatially higher than other available mesh designs.

55. Defendants had sole access to material facts concerning the defective nature of the Surgimesh mesh and its propensity to cause serious and dangerous side effects.

56. Defendants failed to report information regarding the propensity of the SurgimeshXB to fail and cause injury and have made unfounded representations regarding the efficacy and safety of the SurgimeshXB.

57. In reliance on Defendants' representations, Plaintiff s doctors were induced to, and did use the Defendants' SurgimeshXB.

58. As a result of Defendants' conduct, Plaintiff has incurred and will continue to incur future medical costs related to the SurgimeshXB product.

59. As a result of Defendants' actions, Plaintiff and her physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff would be exposed to the risks identified in this Complaint, and that those risks were the direct and proximate result of Defendants' conduct.

60. As a direct result of being implanted with SurgimeshXB, Plaintiff has been permanently and severely injured.

61. Plaintiff requires and will in the future require ongoing medical care and treatment, including the possibility of future surgeries.

62. Plaintiff, as a direct and proximate result of the SurgimeshXB, suffered severe physical pain and suffering, including distress, and has and will sustain permanent injuries and emotional distress, along with economic loss due to medical expenses, and living-related expenses due to her injuries.

COUNT I
NEGLIGENCE

63. Plaintiff re-alleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

64. At the time, Defendants designed, manufactured, promoted, and distributed the SurgimeshXB implanted in Plaintiff, Defendants were engaged in the business of selling such hernia mesh devices and the device was expected to and did reach Plaintiff's prescribing physician and plaintiff without substantial change in condition from when it was sold and distributed.

65. At all relevant times, Defendants had a duty to exercise reasonable and ordinary care in the manufacture, design, labeling, instructions, warnings, sale, marketing, distribution and post-market surveillance of the SurgimeshXB product.

66. Defendants breached the duty of care to the Plaintiff, as aforesaid, in the manufacture, design, labeling, warnings, instructions, sale, marketing, distribution, and post-market surveillance of the device.

67. Defendants breached their duty by failing to comply with state and federal regulations concerning the study, testing, design, development, manufacture, inspection, production, advertisement, marketing, promotion, distribution, and/or sale of the SurgimeshXB product.

68. Defendants breached their duty as the SurgimeshXB was not fit for the ordinary purposes for which it was intended, hernia repair with intraperitoneal placement, and did not meet the reasonable expectation of an ordinary consumer as to its safety at the time it was manufactured and distributed.

69. Additionally, at the time the SurgimeshXB implanted in Plaintiff was manufactured and distributed, there were safer, practical, alternative designs available, the utility of which outweighed the utility of the SurgimeshXB. For example, there are other hernia mesh designs that employ far more effective barrier designs to prevent the type of injuries experienced by Plaintiff.

70. As a direct and proximate result of the duties breached, the Surgimesh failed, causing much pain and suffering experienced by Plaintiff, along with mental anguish, doctor visits, subsequent procedures, and substantial medical bills.

71. As a direct and proximate result of Defendants' negligence, Plaintiff suffered severe pain, injuries and damages.

72. As a direct and proximate result of Defendants' conduct, Plaintiff has suffered and will continue to suffer severe pain and mental anguish.

73. Defendants' conduct in continuing to market, sell and distribute the Surgimesh after obtaining knowledge that the products were failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the safety of others, justifying an

award of additional damages for aggravating circumstances in such a sum which will serve to deter Defendant and others from similar conduct in the future.

74. Defendants knew or should have known that its failure to exercise ordinary care in the manufacture, design, labeling, warnings, instructions, sale, marketing, distribution and recruitment and training of physicians to implant the Surgimesh would cause foreseeable harm, injuries and damages to individuals such as Plaintiff who are implanted with Surgimesh.

75. As a direct, proximate and foreseeable result of the Defendants' design, manufacture, labeling, marketing, sale, and distribution of the Surgimesh, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

76. Each act or omission of negligence was a proximate cause of the damages and injuries to Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendants, and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT II
STRICT PRODUCTS LIABILITY DESIGN DEFECT

77. Plaintiff re-alleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

78. Defendant supplied, manufactured, sold, distributed and/or otherwise placed into the stream of commerce the Surgimesh implanted into Plaintiff. The product was defective in its design in that when it left the hands of Defendant, it was not safe for its anticipated use and safer, practical and safer alternative designs existed that could have been utilized by Defendant. A reasonably prudent medical device manufacturer would not have placed the Surgimesh with its defective design into the stream of commerce.

79. The Surgimesh was defectively designed when supplied, sold, distributed and/or otherwise placed into the stream of commerce when it was implanted in Plaintiff.

80. The Surgimesh was unreasonably dangerous, taking into consideration the utility of said product and the risks involved in its use. The foreseeable risks associated with the design of the product were more dangerous than a reasonably prudent consumer such as Plaintiff and/or her physician would expect when the product was used for its normal and intended purpose.

81. The Surgimesh reached Plaintiff's implanting surgeon and was implanted in Plaintiff without any substantial change in the condition in which it was supplied, distributed, sold and/or otherwise placed into the stream of commerce.

82. The Surgimesh failed to perform as safely as an ordinary consumer and/or her physician would expect when used as intended or when used in a manner reasonably foreseeable by the manufacturer, and the risks and dangers of the Surgimesh outweigh its benefits. The design defects in the Surgimesh were not known, knowable and/or reasonably apparent to Plaintiff and/or her physician or discoverable upon any reasonable examination. The Surgimesh was used and implanted in the manner in which it was intended to be used and implanted by Defendants pursuant to the instructions for use and the product specifications provided by Defendants.

83. The defective and unreasonably dangerous condition of the Surgimesh was the proximate cause of the damages and injuries complained of by Plaintiff.

84. As a direct and proximate result of the Surgimesh's aforementioned design defects, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

85. Defendants are strictly liable to Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendants and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT III
MANUFACTURING DEFECT

/ / /

86. Plaintiff re-alleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

87. Defendants supplied, manufactured, sold, distributed and/or otherwise placed into the stream of commerce the Surgimesh implanted in Plaintiff. The Surgimesh was defective in its manufacture and construction when it left the hands of Defendant in that its manufacture and construction deviated from good manufacturing practices and/or manufacturing specifications as would be used and/or maintained by a reasonably prudent and careful medical device manufacturer.

88. The Surgimesh as manufactured and constructed by Defendants was unreasonably dangerous to end consumers including Plaintiff and posed an unreasonable degree of risk, danger and harm to Plaintiff.

89. The Surgimesh was expected to reach and did reach Plaintiff's implanting surgeon and Plaintiff without substantial change in the condition in which it was manufactured, supplied, distributed sold and/or otherwise placed in the stream of commerce.

90. The manufacturing defect in the Surgimesh implanted in Plaintiff was not known, knowable or readily apparent to Plaintiff's physician or to Plaintiff. Nor was it discoverable upon any reasonable examination by Plaintiff's physician or Plaintiff. The Surgimesh was used and implanted in the very manner in which it was intended to be used and implanted by Defendant in accordance with the instructions for use and specifications provided by Defendants.

91. The Surgimesh implanted in Plaintiff was different from its intended design and failed to perform as safely as a product manufactured in accordance with the intended design would have performed.

92. The defective and unreasonably dangerous condition of the Surgimesh product was a proximate cause of damages and injuries suffered by Plaintiff.

93. As a direct and proximate result of the Surgimesh's aforementioned manufacturing defect, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain

and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

94. Defendant is strictly liable to Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendant and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT IV
FAILURE TO WARN

95. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

96. Defendants manufactured, designed, marketed, sold and/or otherwise placed into the stream of commerce their Surgimesh product.

97. The Defendants failed to properly and adequately warn and instruct Plaintiff and her prescribing physician that the SurgimeshXB was not safe and effective for its intended and reasonably foreseeable use or of the severity and likelihood of injury it posed to consumers that Defendants knew or should have known at the time the SurgimeshXB implanted in Plaintiff was manufactured and distributed.

98. Defendants also failed to warn or disclose that its many marketing claims regarding the safety and efficacy of the SurgimeshXB were not in fact true, including that the device was the optimal design, would reliably and consistently prevent adhesions to bowel and omentum, would fully incorporate, had lower complications and better outcomes than all other hernia mesh designs, would not cause chronic pain, would not shrink or contract, would prevent infection.

99. While Defendants Instruction for use provide some general warnings of "possible" complication associated with any hernia mesh device, those warnings offer not indication that Defendants knew these events were in fact occurring and how often, and do nothing to correct the many false and deceptive claims made in the marketing and labeling materials. There is also no

warning of dense adhesions to bowel or omentum, erosion or perforation of internal organs, no warning of chronic pain, and no warning of bowel obstruction.

100. Indeed, the Instructions For Use actually downplay the risk posed by adhesions by not including it as a "main risk" but rather only as a "possible risk" and then only noting "visceral attachment."

101. The reality is that Defendants knew the silicone adhesion barrier designed to prevent the mesh from adhering to the bowel, colon and omentum did not work, yet did nothing to warn plaintiff's prescribing physician of this issue.

102. Defendants further failed to inform and further warn Plaintiff and her prescribing physician with respect to the most effective proper technique and methods of implantation and/or the selection of appropriate candidates to receive SurgimeshXB.

103. The Defendants also failed to properly and adequately warn and instruct Plaintiff and her prescribing physician that inadequate research and testing of the SurgimeshXB was done prior to Surgimesh being placed on the market and in the stream of commerce, and that Defendants lacked a safe, effective procedure for removal of the Surgimesh once complications from same arise.

104. The Defendant intentionally, recklessly, and maliciously misrepresented the efficacy, safety, risks, and benefits of SurgimeshXB, understating the risks and exaggerating the benefits in order to advance their own financial interest, with wanton and willful disregard for the rights, safety and health of Plaintiff.

105. The dangerous and defective conditions in the SurgimeshXB existed at the time they were delivered by the manufacturer to the distributor. At the time Plaintiff had her implant surgery, the Surgimesh was in the same condition as when manufactured, distributed and sold.

106. Neither Plaintiff or her prescribing physician knew at the time of surgery that the SurgimeshXB placed during Plaintiff's surgery or at any time prior thereto, of the existence of the defects or dangerous propensities in the SurgimeshXB.

107. Had Defendants provided adequately warnings regarding the severity and likelihood of risks posed by the SurgimeshXB, Plaintiff's prescribing physician would not have used the device. Alternatively, said prescribing physician would have disclosed these warnings to Plaintiff and Plaintiff would not have consented to the use of the device.

108. As a direct and proximate result of the Defendants' design, manufacture, marketing, sale, and distribution of the SurgimeshXB, Plaintiff has been injured and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

109. The Defendants are strictly liable in tort to the Plaintiff for their wrongful conduct in failing to properly warn Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory damages, interest, attorneys' fees, costs of suit, and such further relief as the Court deems equitable and just.

COUNT V
BREACH OF EXPRESS WARRANTY

110. Plaintiff re-alleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

111. At all relevant and material times, Defendants manufactured, marketed, sold, distributed and otherwise placed into the stream of commerce the SurgimeshXB product.

112. In advertising, marketing and otherwise promoting SurgimeshXB to physicians, hospitals and other healthcare providers, including Plaintiff's prescribing physician, Defendants' expressly warranted that their SurgimeshXB was safe and effective for use; was the best and safest design available, would reliably and consistently prevent adhesions to bowel and omentum, would fully incorporate, had lower complications and better outcomes than all other hernia mesh designs, would not cause chronic pain, would not shrink or contract, and would prevent infection. In advertising, marketing and otherwise promoting SurgimeshXB, Defendant intended that physicians, hospitals and other healthcare providers rely upon their representations in an effort to induce them to use SurgimeshXB for their patients.

113. The Plaintiff was a person whom the defendants could reasonably have expected to use, consume, or be affected by the Defendant's SurgimeshXB product, as the Defendant specifically designed the SurgimeshXB for implantation in patients requiring reinforcement of abdominal wall defects such as Plaintiff.

114. With respect to Plaintiff, Defendant intended that SurgimeshXB be implanted in Plaintiff by her treating surgeon in the reasonable and foreseeable manner in which it was implanted and in accordance with the instructions for use and product specifications provided by Defendants. Plaintiff was in privity with Defendants as her prescribing physician stands in her shoes.

115. Defendants breached express representations and warranties made to Plaintiff and her physicians and healthcare providers with respect to the SurgimeshXB implanted in Plaintiff including the following particulars:

a) Defendant represented to Plaintiff and her physicians and healthcare providers through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions among other ways that the Defendants' SurgimeshXB was safe, meanwhile Defendant fraudulently withheld and concealed information about the substantial risks of serious injury associated with using SurgimeshXB;

b) Defendant represented to Plaintiff and her physicians and healthcare providers that the Defendants' SurgimeshXB was as safe and/or safer than other alternative procedures and devices then on the market, meanwhile Defendant fraudulently concealed information that demonstrated that SurgimeshXB was not safer than alternative therapies and products available on the market; and

c) Defendant represented to Plaintiff and her physicians and healthcare providers that the Defendants' SurgimeshXB was more efficacious than other alternative procedures, therapies and/or devices. Meanwhile Defendant fraudulently concealed information, regarding the true efficacy of SurgimeshXB.

116. At the time of making such express warranties, Defendants knew or should have known that Defendants' SurgimeshXB does not conform to the express warranties, and Defendants' acts were motivated by financial gain while the adverse consequences of Defendants' conduct was outrageous, fraudulent, oppressive, done with malice or gross negligence and evidenced reckless indifference to Plaintiff's rights, health and safety.

117. As a direct and proximate result of Defendants' breaches of the aforementioned express warranties, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, impairment of personal relationships, and other damages.

WHEREFORE, Plaintiff demands judgment against Defendant and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VI
FRAUD AND CONCEALMENT

118. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

119. Defendants marketed the SurgimeshXB devices implanted in Plaintiff, to her prescribing physician, Dr. Scott Cassidy, by in person sales calls, providing him brochures, providing him favorable studies and case reports, and by providing labeling materials, including in the box in which Plaintiff's SurgimeshXB was contained.

120. As discussed above, Defendants' made numerous knowingly or recklessly false statements to Dr. Cassidy in these communications with the intent of influencing Dr. Cassidy to use and prescribe the SurgimeshXB device. These false statements include, but are not limited to, the following:

a. SurgimeshXB provides superior patient outcomes compared to all other hernia mesh devices;

b. SurgimeshXB is the optimal hernia mesh design and allows for optimal outcomes, reduced patient complication rates, reduced recurrence rates, and has the safest track record compared to other hernia mesh devices;

c. SurgimeshXB's design would reliably prevent adhesions from forming to the device and decreased the risk of adhesions compared to other barrier mesh devices;

d. SurgimeshXB's design would lead to complete, strong, and full incorporation of the mesh into the abdominal wall, and that this would occur within 12 days;

e. SurgimeshXB's design provides superior incorporation compared to all other hernia mesh devices;

f. SurgimeshXB's design prevents any noticeable amount of shrinkage/contraction of the device after implantation unlike other hernia mesh devices.

g. SurgimeshXB's design leads to a flexible repair that prevents patient pain from the device unlike other hernia repair devices;

h. SurgimeshXB's design protects the device from infection;

i. SurgimeshXB's design limits inflammatory response to low levels and will not cause shrinkage/contraction;

j. That SurgimeshXB is a lightweight hernia mesh design and thus will not cause significant foreign body response or patient pain.

121. The truth of these matters were solely in the possession the Defendants.

122. Dr. Cassidy was not aware and had no way to be aware that these statements were not true.

123. Dr. Cassidy took these statements as true and would not have prescribed the device to Plaintiff.

124. Similarly, had Defendants not concealed that its many marketing claims regarding the safety and efficacy of the SurgimeshXB were not in fact true, including that the device was the optimal design, would reliably and consistently prevent adhesions to bowel and omentum, would fully incorporate, had lower complications and better outcomes than all other hernia mesh designs,

would not cause chronic pain, and would not shrink or contract, Dr. Cassidy would not have prescribed the device to Plaintiff.

125. These misrepresented and concealed facts were material to Dr. Cassidy's decision to prescribe the SurgimeshXB to Plaintiff.

126. Defendants withheld this information from Dr. Cassidy with the intent to induce him to prescribe the device to patients, including Plaintiff, which he did.

127. As a direct and proximate result of Defendants' intentional and reckless fraudulent statements and concealment of material facts, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, impairment of personal relationships, and other damages.

WHEREFORE, Plaintiff demands judgment against Defendant and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VII
GROSS NEGLIGENCE

128. Plaintiff re-alleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

129. According to the Illinois Pattern Jury Instructions, IPJI 14.01, gross negligence is "willful and wanton conduct" showing actual or deliberate intention to harm or an utter indifference to or conscious disregard for a person's own safety and the safety of others.

130. The acts and omissions of Defendant as alleged herein are of a character and nature that is outrageous, fraudulent, oppressive, done with malice and evidenced reckless disregard for Plaintiff's rights, health and safety and constitute gross negligence and/or willful or intentional indifference or conduct.

131. The acts and omissions of Defendant, whether taken singularly or in combination with others, constitute gross negligence or willful and/or intentional conduct that proximately caused injuries to Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendant and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

VICARIOUS LIABILITY

132. Whenever in this complaint it is alleged that Defendants did or omitted to do any act, it is meant that Defendants' officers, agents, servants, employees, or representatives did or omitted to do such act and that at the time such act or omission was done, it was done with the full authorization or ratification of Defendants or was done in the normal and routine course and scope of employment of Defendants' officers, agents, servants, employees, and representatives.

EQUITABLE TOLLING OF THE APPLICABLE STATUTE OF LIMITATION

133. The running of any statute of limitation has been tolled by reason of the Defendants' fraudulent conduct. Defendants, through affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's treating physicians the true risks associated with Surgimesh.

134. As a result of the Defendants' actions, Plaintiff and Plaintiff's treating physicians were unaware, and could not reasonably know or have learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.

135. Furthermore, Defendants are estopped from relying on any statute of limitations defense because of their fraudulent concealment of the truth regarding the quality and nature of Surgimesh. Defendants had a duty to disclose the true character, quality and nature of Surgimesh because this was non-public information over which Defendants had and continued to have exclusive control, and because Defendants knew that this information was not available to the

Plaintiff, medical providers and/or to health facilities. Defendants is estopped from relying on any statute of limitation because of their intentional concealment of these facts.

136. The Plaintiff had no knowledge that Defendants was engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment and wrongdoing by Defendants, Plaintiff could not have reasonably discovered the wrongdoing until less than the applicable limitations period prior to the filing of this action.

PRAYER FOR RELIEF

Plaintiff demands judgment against Defendants and prays for the following relief in accordance with applicable law and equity:

i. Compensatory damages to Plaintiff for past, present, and future damages, including, but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiff, permanent impairment, emotional distress and anxiety, loss of enjoyment of life, past and future health and medical care costs and economic damages including past and future lost earnings and/or earning capacity together with interest and costs as provided by law;

ii. Reasonable attorneys' fees to the extent allowed by law;

iii. The costs of these proceedings, including past a future cost of the suit incurred herein;

iv. Prejudgment interest on all damages as is allowed by law;

v. Punitive Damages as to all Counts except Breach of Express and Implied Warranties.

vi. Such other and further relief as this Court deems just and proper.

/ / /

/ / /

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury on all issues so triable.

Respectfully submitted,

PLAINTIFF TAMMY KEEL

By her attorneys,

October 7, 2022

By: */s/ Alan J. Bernstein*

Alan J. Bernstein
Law Offices of Alan J. Bernstein, Ltd.,
10 S. LaSalle St., Ste. 1420,
Chicago, IL 60603
Telephone: 312-726-2755

Troy A. Brenes, Esq.
(Pro Hac Vice pending)
BRENES LAW GROUP
100 Spectrum Center Drive, Suite 330
Irvine, CA 92618
Tel: (949) 397-9360
Fax: (949) 607-4192
tbrenes@breneslawgroup.com